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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/775,964

02/10/2004

Jia-Hwa Fang

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1609

7590

02/04/2005

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EXAMINER

FUBARA, BLESSING M.

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 02/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/775,964

Applicant(s)

FANG ET AL.

Examiner

Blessing M. Fubara

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1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>02/10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Examiner acknowledges receipt of amendment and remarks filed 11/08/05. Claims 34-44 are pending.

The previous objection to claims 37-40 is withdrawn in light of the amendment and the new rejection below.

Information Disclosure Statement

Examiner acknowledges the prior art documents submitted in the parent application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

2. Claims 34-44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
3. Claims 34, 37, 39, 40 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements. See MPEP § 2172.01. Paragraph [0025] on page 6 of the disclosure indicates that when the weight of the detergent to the weight of the polymer is from about 0.001:1 to about 0.05:1, filtration or washing step is not necessary in order to remove excess detergent. Further on page 7, and continuation of paragraph [0025], it is stated that when the weight of the cationic detergent, CTAB, to the weight of the polymer, poly (D,L-lactide-co-glycolide), is from about 0.002:1 to 0.04:1, "the microparticles are not subjected to a step to remove excess CTAB from the composition." Thus, the disclosure stipulates that the amount of the detergent to the polymer has to be low (see paragraph [0025] of the disclosure) to avoid a

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washing step that would remove excess detergent. However, the claim does not indicate the limit of detergent amount at which there would not be a washing step. The scope of the claims is thus not commensurate with what is disclosed to be essential to avoid filtration or washing.

Claim Rejections - 35 USC § 102

4. Claims 34, 35 and 42-44 remain rejected under 35 U.S.C. 102(e) as being anticipated by Levy et al. (US 6,395,253).

Claim Rejections - 35 USC § 103

5. Claims 36, 37, 39 and 41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (US 6,395,253).

Applicants argue that the examples in Levy washes the microparticles, specifically three times, while in the instant case the microparticles are not washed.

6. Applicants' arguments filed 11/08/04 have been fully considered but they are not persuasive.

Specifically, Example 5.2.1 discloses the washing step. However, Examples 5.1, 5.3 do not disclose washing steps and in the column 19, lines 24-26, Levy specifically discloses that the presence of 0.1% of SDS, which is a detergent required for the DNA containing microsphere to disrupt. It is respectfully noted that the washing step in the instant application is necessary to remove excess detergent. It is also noted that there is no starting amount of detergent recited in the claims and the 0.1% of detergent falls within the 10-90 % of the total detergent.

7. Claims 34, 35, 42 and 43 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Hagan et al. (US 6,086,901).

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O'Hagan discloses the process of preparing an emulsion that comprises poly(lactide-co-glycolide), solvent and detergent (Example 1); O'Hagan discloses that the size of the droplets (particle, microsphere) depends on the ratio of the detergent to oil (column 12, lines 38-47) and also that water-in-oil-water (w/o/w) type emulsion can be formed of the microparticle (column 10, lines 9-20). O'Hagan does not disclose a wash step. O'Hagan meets the limitations of the claims.

8. Claims 38, 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Levy et al. (US 6,395,253) in view of Paliard et al. (US 6,562,346).


Levy has been previously discussed. Levy does not disclose cetyl trimethyl ammonium bromide (CTAB) detergent. But Paliard discloses an emulsion that comprises PLG polymer and CTAB (example 5). Thus Paliard is relied upon for a teaching that the specific CTAB detergent can be used with PLG in an emulsion. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare the double emulsion of Levy where the emulsion comprises a detergent and PLG and a solvent. One having ordinary skill in the art would have been motivated to use the CTAB of Paliard in place of SDS with the expectation that the CTAB will interact with the composition to aid the DNA containing microsphere to disrupt to release the DNA.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara 
Patent Examiner
Tech. Center 1600